

**PETITION FOR EVALUATION AND APPROVAL OF
REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY
PART A: GENERAL INFORMATION**



Name of Company			
Name of Petitioner (Must be an individual(s) Name)			
Trade Name of Device		Model Number	
Petitioner Address			
City	State	ZIP Code	Petitioner Telephone Number

Department Use Only

Date Application and Questionnaire Received	Date Complete
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Note: The review and assessment process will not commence until all information required is submitted by the petitioner and received by the Department.

EVALUATION OF MEDICAL WASTE TREATMENT TECHNOLOGY INFORMATION REQUEST FORM

Complete the following questionnaire and return it along with the application. Please include any additional support data that may be applicable. Use additional paper if necessary. Reference with the related section and number(s).

A. GENERAL

A1.	Is the alternative treatment technology best suited for onsite use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving waste from several generators?
	<input type="checkbox"/> Onsite <input type="checkbox"/> Commercial/Regional <input type="checkbox"/> Both
A2.	Is this treatment technology specified for use at small generator facilities such as physician, dental, or veterinary offices or clinics?
	<input type="checkbox"/> No <input type="checkbox"/> Yes
A3.	Has this alternative treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.

B. LEVEL OF TREATMENT

B1.	Does the level of microbial inactivation achieved by the treatment process meet the following definition:
	“Inactivation of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log ₁₀ reduction or greater, and <u>B. stearothermophilus</u> spores or <u>B. subtilis</u> spores at a 4 Log ₁₀ reduction or greater.”?
	<input type="checkbox"/> Yes <input type="checkbox"/> No – If no, specify where the definition is unfulfilled.
	<hr/>
	<hr/>
	<hr/>
	<hr/>
	<hr/>

C. CHARACTERIZATION OF PROPOSED TREATMENT PROCESS

C1. Please check the appropriate categories that best describe the methods of this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

- | | | |
|--|--------------------------------------|-------------------------------------|
| <input type="checkbox"/> Chemical | <input type="checkbox"/> Heat | <input type="checkbox"/> Plasma Arc |
| <input type="checkbox"/> Encapsulation | <input type="checkbox"/> Irradiation | <input type="checkbox"/> Radiowave |
| <input type="checkbox"/> Grinder | <input type="checkbox"/> Mechanical | <input type="checkbox"/> Shredder |
| <input type="checkbox"/> Hammermill | <input type="checkbox"/> Microwave | |
| <input type="checkbox"/> Other(specify)_____ | | |

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

Please identify whether the proposed system is compatible or non-compatible with the following types of waste.

	Types of Waste	Compatible	Non-compatible
D1.	Cultures and stocks of infectious agents and associated biologicals	<input type="checkbox"/>	<input type="checkbox"/>
D2.	Liquid human and animal waste including blood and blood products and body fluids	<input type="checkbox"/>	<input type="checkbox"/>
D3.	Human anatomical waste, tissues and body fluids	<input type="checkbox"/>	<input type="checkbox"/>
D4.	Contaminated waste from animals	<input type="checkbox"/>	<input type="checkbox"/>
D5.	Sharps	<input type="checkbox"/>	<input type="checkbox"/>

Please refer to the State medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D6. What waste characteristics present the most challenge to the proposed treatment process?

☐ Organic materials ☐ Liquids ☐ Density/compaction

☐ Other characteristics (Specify)_____

D7. Describe by composition (i.e., material and percentage) those medical wastes that would provide the most challenge to the proposed technology. Why?

E. BY-PRODUCTS OF THE TREATMENT PROCESS

E1.	Please indicate all by-products which may be generated as a result of this alternative treatment technology.			
	<input type="checkbox"/> Air Emissions	<input type="checkbox"/> Heat	<input type="checkbox"/> Slag	<input type="checkbox"/> Vapors or Fumes
	<input type="checkbox"/> Ash	<input type="checkbox"/> Liquid	<input type="checkbox"/> Smoke	
	<input type="checkbox"/> Dust	<input type="checkbox"/> Odor	<input type="checkbox"/> Steam	
	<input type="checkbox"/> Other (Specify) _____			
E2.	If any of the above by-products are indicated, how will they be controlled?			
E3.	If there are no by-products indicated, how was this determined?			
E4.	Are any of these by-products toxic, biohazardous, etc.? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.			

F. MICROBIOLOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, viruses, and mycobacteria at a 6 Log₁₀ reduction or greater. A representative from each microbial group is required for testing.

Fl. Lister below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are data to support the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

Vegetative Bacteria

- ☐ Staphylococcus aureus (ATCC 6538)
- ☐ Pseudomonas aeruginosa (ATCC 15442)

Fungi

- ☐ Candida albicans (ATCC 18804)
- ☐ Penicillium chrysogenum (ATCC 24791)
- ☐ Aspergillus niger

Viruses

- ☐ Polio 2 or Polio 3
- ☐ MS-2 Bacteriophage (ATCC 15597-B1)

Parasites

- ☐ Cryptosporidium spp. Oocysts
- ☐ Giardia spp. Cysts

Mycobacteria

- ☐ Mycobacterium terrae
- ☐ Mycobacterium phlei
- ☐ Mycobacterium bovis (BCG) (ATCC 35743)

Bacterial Spores

- ☐ B. stearothermophilus (ATCC 7953)
- ☐ B. subtilis (ATCC 19659)

F. MICROBIOLOGICAL TEST PROCEDURES (CONTINUED)

- F1. Were the results certified by an independent, public health or certified testing laboratory?
☐ No ☐ Yes – If so, indicate the name, address, telephone number of the
certifying laboratory and attach test protocol and results.

G. CHEMICAL INACTIVATION TREATMENT PROCESSES

- G1. If the treatment involves the use of chemical inactivation:
a) What is the name of the active ingredients? _____
b) What concentrations must be used and maintained? _____
c) At what Ph is the chemical agent active? _____
d) What is the necessary contact time? _____
e) If there is any incompatibility with specific materials and surfaces, specify. ____
- G2. What is the active life of the chemical agent after it has been exposed to air or
contaminated medical waste?

- G3. Have studies been conducted relative to the long-term effectiveness of the chemical agent
while in use?
? No ? Yes - If yes, please attach a copy of the study and test results.
- G4. What health and safety hazards may be associated with the chemical (present and long-
term)? Specify _____
MSDS Attached? ? No ? Yes
- G5. Is the chemical agent registered for this specific use with the Environmental Protection
Agency (EPA) Pesticide Registration Division?
? No ? Yes - If yes, provide the EPA registration number _____
- G6. Is the spent chemical agent classified as a hazardous waste by U.S. EPA (40 CFR Part
261) or by other state criteria?
? No ? Yes - If yes, specify whether by USEPA or which state _____
- G7. Is an environmental impact study for the chemical agent available?
? No ? Yes - If yes, attach a copy of this information.

H. ENVIRONMENTAL EFFECTS ON THE TREATMENT PROCESS

H1.	Can positive or negative effects on the environment be anticipated from the use and/or disposal of the treated waste from the treatment process? ? No ? Yes - If yes, specify _____
H2.	What environmental, occupational, and/or public hazards would be associated with a malfunction of the treatment process? Specify _____
H3.	If the treatment process includes the use of water, steam, or other liquids; how will this waste discharge be handled (i.e., sewer, recycle, etc.)? Specify _____
H4.	How will the treated waste from this process be disposed of (i.e., landfill, incineration, recycle, etc.)? Specify _____
H5.	Are the by-products identified as a hazardous waste? ? No ? Yes - Complete item M1

I. CRITICAL FACTORS OF TREATMENT PROCESS

I1.	What are the critical factors that influence the specific treatment technology? Specify _____
I2.	What are the consequences if these factors are not met? Specify _____
I3.	Explain the ease and/or difficulty of operation of the medical waste treatment system? Specify _____
I4.	What type of ongoing maintenance is required in the operation of the treatment system? Specify _____ Maintenance Manual Attached? ? No ? Yes
I5.	What emergency measures would be required in the event of a malfunction? Specify _____
I6.	Are these measures addressed in an emergency plan or in the operations protocol? ? No ? Yes - If yes, attach a copy
I7.	What is the maximum amount of waste to be treated by this process per cycle? _____
I8.	How long is a cycle? _____

J. QUALITY ASSURANCE AND VERIFICATION OF ADEQUATE TREATMENT

- J1. How is the quality assurance of the treatment process addressed?
Specify _____
- J2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system?
Specify _____
- J3. Other than the biological indicators listed in Section F, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? (Please describe and explain.)
- J4. How is it determined that the processed waste has received proper treatment?
(Check the appropriate item.)
- Temperature indicator: ? Visual only ? Continuous ? Both
- Pressure indicator: ? Visual only ? Continuous ? Both
- Time indicator: ? Visual only ? Continuous ? Both
- Chemical concentration indicator: ? Visual only ? Continuous ? Both
- ? Other - Please specify _____
- J5. Have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process?
Specify _____
- J6. Is there a process monitor calibration schedule established, and at what frequency is calibration performed?
- J7. Are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.
- J8. Are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately effected? Explain.

K. POST TREATMENT RECYCLING

- K1. Has a strategy been developed for the recycling of any part of the treated waste?
☐ No ☐ Yes If yes, please include additional information regarding the strategy.

L. COMPLIANCE WITH MEDICAL WASTE REGULATIONS

- L1. Does your treatment technology meet the requirements of the State's medical waste regulations for medical waste decontamination and disposal?
? No ? Yes

- L2. Which of the following five categories of medical waste will be effectively treated by your system? (Check all that apply.)

	NO	YES
a) Cultures and Stocks	?	?
b) Blood and Blood Products and Body Fluids	?	?
c) Human Anatomical Waste, Human Tissues and Body Fluids	?	?
d) Sharps	?	?
e) Contaminated Animal Wastes	?	?

M. INTERAGENCY COORDINATION

- M1. Have you inquired from the State's medical waste permit coordinator as to whether any other permits are required? ? No ? Yes
If yes, please enclose the response and requirements with your application.

NOTE: Local governments may require permits.

N. POTENTIAL ENVIRONMENTAL BENEFITS

N1. Has an energy analysis been conducted on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N2. Has an economic analysis been performed on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N3. How does this treatment technology improve on existing medical waste treatment and disposal methods?

Specify _____

N4. What is the potential of this proposed technology for:

Waste volume reduction? Specify _____

Recycling? Specify _____

O. OTHER RELEVANT INFORMATION AND COMMENTS

(Approvals received from other states, operator safety, competency or training requirements for the users/operators, etc.)

**PETITION FOR EVALUATION AND APPROVAL OF
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PART B: ATTACHMENTS**

The general information contained in Part A and this check sheet are a required part of the petition package. These assist the petitioner in submitting the petition and the Department in its review, and they are supplemental to the required documents listed below. The complete petition package consists of a completed Part A form, this Part B check sheet, all the documents listed below, and any other supportive data or information the petitioner wishes to be considered.

- ? Petitioner's submittal certification
- ? Quality Assurance and Quality Control Report
- ? Microbiological testing report
- ? Material Safety Data Sheets
- ? Environmental Protection Agency pesticide registration documents

- ? Maintenance manual
- ? Emergency operations manual
- ? Operations manual
- ? Design plans and specification